

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Atty Docket No. 046714/0113

In re: U.S. Patent No. 5,362,755

Patentee: Timothy J. BARBERICH et al.

Assignee: Sepracor, Inc.

Issue Date: November 8, 1994

**STATUS INQUIRY****FAX RECEIVED**Commissioner for Patents and Trademarks  
Washington, D.C. 20231

APR 01 2003

PETITIONS OFFICE

Applicants respectfully inquire as to the status of the above-referenced patent term extension. The patent has an issue date of November 8, 1994. A Request for Extension of Patent Term Under 35 U.S.C. §156 was filed May 21, 1999. The last known communication regarding this patent was a letter dated December 30, 2002 (copy attached), to The Honorable James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, Food and Drug Administration. To date, no further communication has been received on this application.

Respectfully submitted,

Date April 1, 2003By Stephen B. MaebiusFOLEY & LARDNER  
Customer Number: 22428

22428

PATENT TRADEMARK OFFICE

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**From:** Diana Meinecke Legal Assistant to  
Stephen B. Maebius  
**Sender's Direct Dial:** 202-945-6135  
**Date:** April 1, 2003

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### MESSAGE:

PETITIONS OFFICE

U. S. Patent No. 5,362,755  
Sepracor, Inc.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-0741 in reference to the required Amendment fee.

  
Stephen B. Maebius, Reg. No. 35,264

### CERTIFICATION

I hereby certify that this document is being facsimile transmitted to U.S. Patent and Trademark Office, Attn: Karin Ferriter, Office of Petitions, on the date shown below, (1) Status Inquiry.

4/1/03  
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03/27/03

17:04

## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

NO. 022 002

Public Health Service

Food and Drug Administration  
Rockville MD 20857Re: Xopenex  
Docket No. 99E-5116

The Honorable James E. Rogan  
 Under Secretary of Commerce for Intellectual Property and  
 Director of the United States Patent and Trademark Office  
 Box Pat. Ext.  
 P.O. Box 2327  
 Arlington, VA 22202

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,362,755 filed by Sepracor, Inc., under 35 U.S.C. § 156. The human drug product claimed by the patent is Xopenex (levalbuterol), which was assigned new drug application (NDA) No. 20-837.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigley*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on March 25, 1999, which makes the submission of the patent term extension application on May 21, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

*Jane A. Axelrad*

Jane A. Axelrad  
 Associate Director for Policy  
 Center for Drug Evaluation and Research

cc: Harold C. Wegner  
 Foley & Lardner  
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 Washington, DC 20007-5109

B/E/C  
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